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Dated: 7-1-, 2003

Signature: Linda Bourg  
LINDA BOURG

DT14R PCT/PTO 0 1 JUL 2003

#10

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Nicholas Bachynsky

Woodie Roy

Serial No.: 09/744622 (PCT/US99/16940)

Filed: January 26, 2001

For: **CHEMICALLY INDUCED  
INTRACELLULAR HYPERTHERMIA**

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Group Art Unit: Unknown

Examiner: Unassigned

Atty. Docket: P01615US1 / 09805783  
(U.S. Nat'l. Phase)

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**0 9 JUL 2003**

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**RENEWED PETITION UNDER 37 C.F.R. 1.47(B)**

Dear Sir:

This Renewed Petition Under 37 C.F.R. § 1.47(b), is filed in response to a Decision on Petition dated 05 September 2002, for the above-referenced application, which dismissed the applicants Renewed Petition filed on 27 November 2002, without prejudice. This Renewed Petition addresses issues raised by the PTO in the dismissal to the extent they were not addressed earlier. Applicants were given two months to file this Renewed Petition, subject to extensions under 37 C.F.R. § 1.136(a). The filing of this Renewed Petition Under 37 C.F.R. § 1.47(b), is timely because it is being filed prior to 12 July 2003.

**BACKGROUND OF PTO PROCEEDINGS**

1. On 27 July 1999, applicants filed international application PCT/US99/1690, which claimed a priority date of 27 July 1998, based on a previously-filed provisional application. A copy of the international application was communicated to the United States

Patent and Trademark Office from the International Bureau on 10 February 2000. A Demand for international preliminary examination, in which the United States was elected, was filed on 23 February 2000.

2. On 26 January 2001, applicants filed a transmittal letter for entry into the national state in the United States. However, the applicant did not file an oath or declaration under 35 U.S.C. § 371(c)(4) because the inventors refused to sign one.

3. On 05 March 2001, the United States Designated/Elected Office mailed applicants a "Notification of Missing Requirements Under 35 U.S.C. § 371 in the United States Designated/Elected Office" indicating that an oath or declaration in compliance with 37 C.F.R. § 1.497(a) and (b) was required.

4. On 05 September 2001, applicants filed a Petition Under 37 C.F.R. § 1.47, and a declaration executed by the assignee on behalf of the non-signing inventors.

5. On 08 November 2001, the United States Patent and Trademark Office ("PTO") mailed a Decision Refusing Status Under 37 C.F.R. § 1.47, and dismissed the petition without prejudice.

6. On 07 May 2002, the applicants filed a Renewed Petition Under 37 CFR 1.47(B), along with supporting declarations and documents.

7. On 05 September 2002, the PTO dismissed the Renewed Petition without prejudice.

8. On November 27, 2002, the applicants filed a Renewed Petition Under 37 CFR 1.47(B), along with supporting declarations and documents relating to the proof of unavailability or refusal and proof of proprietary interest.

9. On 12 May 2003, the PTO dismissed the Renewed Petition without prejudice.

#### **DEFICIENCIES NOTED IN 05 SEPTEMBER 02 DECISION**

In its Decision of 12 May 2003, the PTO stated that the petition filed on 27 November 2002, was deficient for the following reasons:

- **Proof of Proprietary Interest** - Petitioner has not demonstrated that applicant has a proprietary interest in the invention. Petitioner has provided an

Assignment executed by Nicholas Bachynsky and Woodie Roy. As stated in the previous petition, the assignments of the "invention" were to Texas Pharmaceutical, Inc., show sufficient proprietary interest, however, the assignments are not acceptable to establish ownership and file the application under 37 CFR 1.47(b). The assignments do not identify the instant application by application number. Applicant has stated that the description of the invention sold in the sales agreement is identical to the invention and the assignment recorded under the priority document. However, Applicant has not stated that the invention in the sales agreement, the priority document, and the instant application are identical.

Applicants have corrected the deficiencies noted above, to the extent they were not satisfied in the earlier petitions, through the accompanying Supplemental Declaration by James Naples, attached as Exhibit 1.

### **STATEMENT OF FACTS**

Petitioner's showings are summarized in the following Statement of Facts:

#### **Proof of Proprietary Interest:**

The following written, documentary evidence is being submitted with this Renewed Petition which shows that the assignee, Texas Pharmaceuticals, Inc., has full proprietary interest in the invention. Dr. Naples has first hand knowledge of the preparation and execution of all of the attached documents, which show that the invention of the above-referenced application has been assigned by inventors to Texas Pharmaceuticals, Inc. and that it otherwise has full proprietary interest in the invention of the above-referenced application.

#### **1. Exhibit A: Declaration by Mr. Naples:**

James J. Naples is the President of assignee and has full authority to execute the declaration on behalf of the assignee.

Submitted herewith as Exhibit 1 is a Declaration executed by Mr. Naples declaring that the invention of the instant application, the priority document (U.S. Provisional Application No. 60/094,286), and the subject matter described in the sales agreement (hereinafter defined as the "Agreement") are identical.

#### **2. Identity of Instant Application, Priority Document, and the Invention Described in the Sales Agreement:**

The instant application, the priority document (U.S. Provisional Application No. 60/094,286), and the subject matter described in the Agreement in Schedule 1 to Exhibit A thereto refer to the same invention.

The Agreement covers, in writing, the sale of rights to the invention as disclosed and claimed in the above-referenced patent application, and U.S. Provisional Application No. 60/094,286, to which the instant application claims priority. This is shown, for example, in the Agreement which describes the sold invention as follows:

Seller [Inventor Nicholas Bachynsky], with the financial support of James J. Naples, has been conducting medical research and developing a novel use and method of inducing intracellular hyperthermia and free radical flux through use of dinitrophenol and other mitochondrial uncoupling agents in the treatment of infectious and malignant disease. Seller has developed and devised a therapeutic application of dinitrophenol and other mitochondrial uncoupling agents for such purposes.

This is the same invention as the above-referenced patent application. This can be seen, for example, from the abstract of the instant application, which defines the invention as follows:

An invention relating to therapeutic pharmacological agents and methods to chemically induce intracellular hyperthermia and/or free radicals for the diagnosis and treatment of infections, malignancy and other medical conditions. The invention relates to a process and composition for the diagnosis or killing of cancer cells and inactivation of susceptible bacteria, parasitic, fungal and viral pathogens by chemically generating heat, and/or free radicals or hyperthermia-inducible immunogenic determinants by using mitochondrial uncoupling agents, especially 2,4 dinitrophenol [dinitrophenol] either alone or in combination with other drugs, hormones, cytokines and radiation.

The abstract of the priority document, U.S. Provisional Application No. 60/094,28, identically describes the invention as described in the instant application:

An invention relating to therapeutic pharmacological agents and methods to chemically induce intracellular hyperthermia and/or free radicals for the diagnosis and treatment of infections, malignancy and other medical conditions. The invention relates to a process and composition for the diagnosis or killing of cancer cells and inactivation of susceptible bacteria, parasitic, fungal and viral pathogens by chemically generating heat, and/or free radicals or hyperthermia-inducible immunogenic determinants by using mitochondrial uncoupling agents, especially 2,4 dinitrophenol [dinitrophenol] either alone or in combination with other drugs, hormones, cytokines and radiation.

Moreover, the working example defining the invention sold in the Agreement, as defined in Schedule 1 to Exhibit A of the Agreement (submitted in the Renewed Petition under 37 CFR 1.47 mailed 27 November 2002), is identical to Example 1 of the above-referenced application (see pages 38 – 40 and Table 15) and identical to Example 1 of the priority document, U.S. Provisional Application No. 60/094,28 (pages 43-45).

**Previously Established Facts Related to Proof of Proprietary Interest:**

**1. Agreement for Sale of Invention and Related Rights – Bachynsky**

Attached as Exhibit A to Exhibit 1 of the Renewed Petition under 37 CFR 1.47 mailed 27 November 2002 is an Agreement for Sale of Invention and Related Rights (by inventor Bachynsky) (“Agreement”), wherein inventor Nicholas Bachynsky sold all right, title and interest in the invention of the above-referenced patent application to assignee, Texas Pharmaceuticals, Inc. This agreement, dated March 2, 1998, was executed and acknowledged by inventor Nicholas Bachynsky on March 5, 1998, and by James J. Naples, on behalf of assignee, on March 6, 1998. This Agreement was executed over one year prior to the filing of the above-referenced patent application and therefore could not include a reference to the patent application or identify the above-referenced patent application by application number.

This document covers, in writing, the sale of rights to the invention as disclosed and claimed in the above-referenced patent application. This is shown, for example, in the Agreement which describes the sold invention as follows:

Seller [Inventor Nicholas Bachynsky], with the financial support of James J. Naples, has been conducting medical research and developing a novel use and method of inducing intracellular hyperthermia and free radical flux through use of dinitrophenol and other mitochondrial uncoupling agents in the treatment of infectious and malignant disease. Seller has developed and devised a therapeutic application of dinitrophenol and other mitochondrial uncoupling agents for such purposes.

This is the same invention as the above-referenced patent application. This can be seen, for example, from the abstract of the instant application, which defines the invention as follows:

An invention relating to therapeutic pharmacological agents and methods to chemically induce intracellular hyperthermia and/or free radicals for the diagnosis and treatment of infections, malignancy and other medical

conditions. The invention relates to a process and composition for the diagnosis or killing of cancer cells and inactivation of susceptible bacteria, parasitic, fungal and viral pathogens by chemically generating heat, and/or free radicals or hyperthermia-inducible immunogenic determinants by using mitochondrial uncoupling agents, especially 2,4 dinitrophenol [dinitrophenol] either alone or in combination with other drugs, hormones, cytokines and radiation.

The invention sold in the Agreement is also defined in Schedule 1 to Exhibit A of the Agreement (submitted in the Renewed Petition under 37 CFR 1.47 mailed 27 November 2002), wherein it is described particularly as follows:

This invention provides a medical treatment for ... treatment of resistant neoplastic and infectious disease by concurrent administration of dinitrophenol [or other mitochondrial thermoregulatory uncoupling agents ...] ... and specific metabolic, activating cytokines ... hormones... and other medications to control and focally enhance the mitochondrial uncoupling effects. ... A new use(s)/method of generating intracellular oxygen derived from free radicals, and heating from within the cell [intracellular hyperthermia] has been discovered for dinitrophenol (or other oxidative phosphorylation uncouplers) in prevention of parasites .. bacteria ... viruses... and neoplasia...”

This description of the invention as sold in the Agreement directly matches the invention described in the present application, as can be seen, for example, from the abstract of the application, quoted above.

Moreover, the working example defining the invention sold in the Agreement, as defined in Schedule 1 to Exhibit A of the Agreement, is identical to Example 1 of the above-referenced application (see pages 38 – 40 and Table 15).

## **2. Assignment by inventor Nicholas Bachynsky**

Exhibit A1 to Exhibit 1 of the Renewed Petition under 37 CFR 1.47 mailed 27 November 2002 is a copy of an Assignment by inventor Nicholas Bachynsky assigning to assignee, Texas Pharmaceuticals, Inc., all right, title and interest in the invention of the present application. As discussed above, the definition of the invention in this assignment is identical to the invention sold by Dr. Bachynsky to assignee and is identical to the invention of the instant application. This assignment was executed by Nicholas Bachynsky on March 4, 1998, many months prior to the filing of the above-referenced patent application on July 27, 1999, and therefore, this assignment could not refer to or identify the application number for the above-referenced patent application, as it did not exist on March 4, 1998.

### **3. Agreement for Sale of Invention and Related Rights -- Roy**

Attached as Exhibit B to Exhibit 1 of the Renewed Petition under 37 CFR 1.47 mailed 27 November 2002 is an Agreement for Sale of Invention and Related Rights (by inventor Roy) ("Agreement#2"), wherein inventor Woodie Roy sold all right, title and interest in the invention of the above-referenced patent application to assignee, Texas Pharmaceuticals, Inc. This agreement, dated July 20, 1998, was executed by inventor Woodie Roy on July 24, 1998, and by James J. Naples, on behalf of assignee, on July 24, 1998. This agreement was executed well in advance of the filing of the above-referenced patent application on July 27, 1999, and therefore could not include a reference to or identify the application number for the above-referenced patent application.

This document covers, in writing, the sale of rights to the invention as disclosed and claimed in the above-referenced patent application. This is shown, for example, in the Agreement which describes the sold invention as follows:

Seller has assisted [inventor] Nicolas Bachynsky ("Bachynsky") who, with the financial support of James J. Naples, has been conducting medical research and developing a novel use and method of inducing intracellular hyperthermia and free radical flux through use of dinitrophenol and other mitochondrial uncoupling agents in the treatment of infectious and malignant disease. Bachynsky and seller have developed and devised a therapeutic application of dinitrophenol and other mitochondrial uncoupling agents for such purposes.

This is the same invention as the above-referenced patent application, which can be seen by reference to the application's abstract (quoted above).

The invention sold in the Agreement#2 is also defined in Schedule 1 to Exhibit A of the Agreement#2, wherein it is defined as follows:

This invention provides a medical treatment for ... treatment of resistant neoplastic and infectious disease by concurrent administration of dinitrophenol [or other mitochondrial thermoregulatory uncoupling agents ...] ... and specific metabolic, activating cytokines ... hormones... and other medications to control and focally enhance the mitochondrial uncoupling effects. ... A new use(s)/method of generating intracellular oxygen derived from free radicals, and heating from within the cell [intracellular hyperthermia] has been discovered for dinitrophenol (or other oxidative phosphorylation uncouplers) in prevention of parasites .. bacteria ... viruses... and neoplasia..."

This description of the invention as sold in the Agreement directly matches the invention described in the present application, as can be seen, for example, from the abstract of the application, discussed above.

Moreover, the working example defining the invention sold in the Agreement#2, as defined in Schedule 1 to Exhibit A of the Agreement#2, is identical to Example 1 of the above-referenced application (see pages 38 – 40 and Table 15).

Further still, the description of the invention sold in the Agreement#2, as defined in Schedule 1 to Exhibit A of the Agreement#2, is identical to the description of the invention of the present invention as found in the attachments to the Assignment of inventor Woodie Roy, as filed in this case

#### **4. Assignment by inventor Woodie Roy**

Exhibit B1 to Exhibit 1 of the Renewed Petition under 37 CFR 1.47 mailed 27 November 2002 is a copy of an Assignment by inventor Woodie Roy assigning to assignee, Texas Pharmaceuticals, Inc., all rights and title to the invention of the present application (as discussed above). As discussed above, the definition of the invention in this assignment is identical to the invention sold by Ms. Roy to assignee and is identical to the invention of the instant application. This assignment was executed well in advance of the filing of the above-referenced patent application on July 27, 1999, and therefore, this assignment could not include a reference to or identify the application number for the above-referenced patent application.

#### **Additional Relevant Facts:**

**1. The inventors signed a declaration for the provisional application.** Mr. Choate has first hand knowledge that both inventors signed a declaration for the provisional patent application which discloses the invention, and is claimed as a priority document in the above-referenced application. This application was also assigned to assignee, as shown in the Assignments previously submitted (recorded with the U.S. Patent and Trademark Office at Reel/Frame 010993/0076 (Bachynsky) and 010992/0945 (Roy)).

**2. James J. Naples is the President of assignee and has full authority to execute the declaration on behalf of the assignee.** James J. Naples is the President of Texas Pharmaceuticals, Inc. and has full authority to execute the declaration on behalf of the assignee.

**3. Filing the above-referenced patent application under 37 C.F.R. § 1.47(b) is necessary to preserve the rights of the parties and to prevent irreparable damage which**



**otherwise would result with the application becoming abandoned.** Dr. Naples' signing the declaration for assignee in lieu of the inventors (filing the application under 37 C.F.R. § 1.47(b)) is necessary in order to preserve the rights of the parties and to prevent irreparable damage which otherwise would result with the application becoming abandoned.

### **CONCLUSION**

For the reasons stated above, and as supported by the attachments hereto, assignee respectfully asserts that the above-referenced application is proper for, and should be accepted with, a declaration under 37 C.F.R. § 1.47(b).

The last known addresses of the inventors, and their attorney, are:


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Please charge the deposit account of Fulbright & Jaworski LLP, Account No. 06-2375, under order no. 09805783 for any fees that may be necessary.

Respectfully submitted,



Jila Bakker

Registration No.: P-53,962

Date: July 1, 2003  
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